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Yiqi Huoxue Chinese herbal medicine plus Western medicine versus Western medicine alone for diabetic peripheral vascular disease in older adults: a systematic review and meta-analysis

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ADMINISTRATIVE INFORMATION

Support - No support.

Review Stage at time of this submission - Data extraction.

Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 29 July 2026 and was last updated on 30 July 2026.

INTRODUCTION

Review question / Objective To evaluate the efficacy and safety of Yiqi Huoxue Chinese herbal medicine combined with Western medicine versus Western medicine alone on ABI, FMD, serum NO, ET-1, clinical response rate, and adverse events in adults aged ≥60 years with type 2 diabetes and diabetic peripheral vascular disease.

Rationale Diabetic peripheral vascular disease (DPVD) is a severe microvascular complication of type 2 diabetes in the elderly, often leading to lower extremity ulcers and even amputation. Although Western medicine (e.g., hypoglycemics, statins) is standard, its efficacy on endothelial function and blood flow restoration is often limited. Yiqi Huoxue (invigorating Qi and activating blood) is a classic TCM therapy that has shown promising effects in improving circulation. However, existing clinical evidence lacks high-quality synthesis. This review aims to systematically evaluate the efficacy and safety of Yiqi Huoxue combined with Western medicine to provide robust evidence for clinical practice.

Condition being studied Type 2 diabetes mellitus complicated by peripheral vascular disease (DPVD) in the geriatric population (aged ≥60 years). It is characterized by atherosclerosis, endothelial dysfunction, and reduced ankle-brachial index (ABI).

METHODS

Search strategy Databases: PubMed, Embase, Cochrane CENTRAL, CNKI, WanFang, VIP, and SinoMed.

Time: From inception to July 2026.

Languages: English and Chinese.

Key terms: ("Diabetes Mellitus, Type 2" OR "Diabetic Angiopathies") AND ("Peripheral Vascular Diseases" OR "Lower Extremity") AND ("Yiqi

Huoxue" OR "Chinese Herbal Medicine") AND ("Randomized Controlled Trial" OR "RCT").

Participant or population ("Diabetes Mellitus, Type 2"[Mesh] OR diabetic)
AND ("Peripheral Arterial Disease"[Mesh] OR "Lower Extremity Arterial Disease" OR LEAD OR PAD)
AND ("Ankle Brachial Index" OR ABI OR "Nitric Oxide" OR "Endothelin-1" OR "Endothelial Function")
AND ("Traditional Chinese Medicine" OR "Yiqi Huoxue" OR "Buyang Huanwu" OR Astragalus OR Huangqi)
AND ("Randomized Controlled Trial"[pt] OR RCT)
AND ("2016/01/01"[Date - Publication] : "2026/07/29"[Date - Publication]).

Intervention Yiqi Huoxue (invigorating qi and promoting blood circulation) Chinese herbal medicine (including decoctions, granules, or proprietary Chinese medicines, e.g., Tangmai Kang, Buyang Huanwu Decoction-based formulas) combined with conventional Western basic treatment (including blood glucose control, statins, antiplatelet drugs, etc.) for elderly patients (≥60 years old) with type 2 diabetic peripheral vascular disease.

Comparator Conventional Western basic treatment alone (identical background therapy as the intervention group, without any Yiqi Huoxue TCM components). Placebo control is also acceptable if specified.

Study designs to be included Only randomized controlled trials (RCTs) evaluating the above intervention vs comparator will be included. Non-RCTs, case reports, reviews, conference abstracts without full text, and animal studies will be excluded.16. Eligibility criteria *.

Eligibility criteria Inclusion: 1) Patients diagnosed with type 2 diabetes + diabetic peripheral vascular disease (DLEVD), aged ≥60 years; 2) RCTs comparing Yiqi Huoxue TCM+Western medicine vs Western medicine alone; 3) Studies reporting at least one of outcomes (ABI, FMD, NO, ET-1, clinical efficacy rate, adverse events).
Exclusion: 1) Non-RCTs, reviews, case reports; 2) Combined with other TCM therapies (acupuncture/moxibustion); 3) Duplicate publications; 4) No available full text/data.

Information sources We will search the following electronic databases from inception to the present: PubMed, Embase, Cochrane Central Register of Controlled Trials (CENTRAL), Web of Science, CNKI, Wanfang Data, and CBM. We will also search relevant clinical trial registries (e.g., ClinicalTrials.gov, Chinese Clinical Trial Registry) and check the reference lists of included studies for additional trials.

Main outcome(s) 1. Ankle-Brachial Index (ABI).
2. Flow-Mediated Dilation (FMD).
3. Serum Nitric Oxide (NO) levels.
4. Endothelin-1 (ET-1) levels.Timing: Assessed at the end of the treatment period (e.g., 4, 8, or 12 weeks).

Additional outcome(s) 1. Clinical total response rate (or Effective rate).
2. Fasting Plasma Glucose (FPG) and Glycated Hemoglobin (HbA1c).
3. Adverse Events (AEs) and Serious Adverse Events (SAEs).
4. Lower extremity symptom scores (if reported).

Data management Data will be managed using Excel and Covidence (or EndNote for reference management). Two reviewers will independently extract data into standardized Excel spreadsheets. Any discrepancies will be resolved by discussion with a third reviewer. Original review records will be kept for at least 5 years after publication.

Quality assessment / Risk of bias analysis The risk of bias (ROB) of included RCTs will be assessed independently by two reviewers using the Cochrane ROB 2.0 tool (Risk of Bias 2.0). Domains include randomization process, deviations from intended interventions, missing outcome data, measurement of the outcome, and selection of the reported result. Disagreements will be resolved by consensus or arbitration by a third reviewer.

Strategy of data synthesis Data analysis will be performed using RevMan 5.4 software. Dichotomous variables (e.g., clinical response rate, adverse events) will be calculated as Risk Ratio (RR) with 95% Confidence Interval (CI). Continuous variables (e.g., ABI, FMD, NO, ET-1, blood glucose) will be calculated as Mean Difference (MD) or Standardized Mean Difference (SMD) with 95% CI. A fixed-effect model will be used if heterogeneity is low (I^2 \le 50\%); otherwise, a random-effects model will be applied.

Subgroup analysis Subgroup analyses will be conducted to explore potential sources of heterogeneity based on: 1) Different types of Yiqi Huoxue interventions (decoction vs. proprietary medicine); 2) Duration of treatment (<8 weeks vs. \ge 8 weeks); 3) Sample size (<100 vs. \ge 100).

Sensitivity analysis Sensitivity analysis will be performed by omitting one study at a time to assess the robustness of the overall results and to identify whether any single study drives the pooled effect estimate.

Language restriction English and Chinese.

Country(ies) involved China.

Other relevant information This is a systematic review and meta-analysis protocol. Ethical approval is not required. The findings will be disseminated through a peer-reviewed journal publication.

Keywords Diabetic Peripheral Vascular Disease; Type 2 Diabetes; Yiqi Huoxue; Chinese Herbal Medicine; Systematic Review.

Dissemination plans The results of this review will be submitted for publication in a peer-reviewed international journal (e.g., BMC Complementary Medicine and Therapies, Journal of Diabetes Research). We will also present the findings at relevant academic conferences if possible.

Contributions of each author

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